

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

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THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

**MEMORANDUM OPINION AND ORDER**  
**(*Daubert* Motion re: Dr. Ralph Zipper, M.D.)**

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Defendant's Motion to Exclude the Opinions and Testimony of Ralph Zipper, M.D. filed by Boston Scientific Corporation ("BSC"). [ECF No. 4816]. Plaintiffs did not respond to the Motion, and the time for responding has expired. Thus, the Motion is ripe for adjudication. As set forth below, BSC's Motion is **GRANTED**.

**I. Background**

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the BSC MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

## II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v.*

*Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

*Daubert* mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We

agree with the Solicitor General that “[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

*Daubert*, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

### III. Analysis

Dr. Zipper is a urogynecologist who is board-certified in female pelvic medicine and reconstruction. Dr. Zipper has performed thousands of transvaginal mesh procedures for the treatment of POP and SUI. He has also explanted over five hundred mesh devices.

Plaintiffs have designated Dr. Zipper as a case-specific expert in eight cases in Wave 3. Despite his designation as a case-specific expert only, his expert reports in each of the eight cases also contain various general causation opinions. BSC challenges these opinions on the grounds that Dr. Zipper is unqualified to offer them, they are unreliable, and they will be unhelpful to the jury. Specifically, BSC

challenges Dr. Zipper's opinions related to product design, characteristics of polypropylene, safer alternative design, adequacy of the warnings on the Directions for Use, and BSC's knowledge or state of mind.

Pursuant to PTO # 171, plaintiffs' expert disclosure was due by October 18, 2017. Because the time for expert disclosure has passed and Dr. Zipper was disclosed only as a specific causation expert, he may not offer general causation testimony, including testimony on the subjects listed above.<sup>1</sup> Accordingly, BSC's Motion [ECF No. 4816] is **GRANTED**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

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<sup>1</sup> Interestingly, BSC does not make the argument that Dr. Zipper should not be permitted to offer general causation opinions because he was disclosed as a case-specific expert only, instead arguing that he is not qualified to offer such opinions and that the opinions are unreliable and unhelpful. Nonetheless, I have previously held in these MDLs that experts who are disclosed for specific causation purposes may not offer general causation testimony. *See, e.g., In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 8727998, at \*2 (S.D. W. Va. Jan. 12, 2017). Because BSC's assertion that Dr. Zipper was disclosed as a case-specific expert only is uncontested by plaintiffs, I reach the same conclusion here.

## EXHIBIT A

Case Number	Case Name
2:17-cv-00294	Grigg v. Boston Scientific Corporation
2:17-cv-00304	Martinez v. Boston Scientific Corporation
2:17-cv-02528	Saldivar v. Boston Scientific Corporation
2:17-cv-02531	Smith v. Boston Scientific Corporation
2:17-cv-02533	Southwood v. Boston Scientific Corporation
2:17-cv-02554	Stark v. Boston Scientific Corporation
2:17-cv-02568	Welsh v. Boston Scientific Corporation
2:17-cv-02571	Wittenborn v. Boston Scientific Corporation